

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Eugenio A. Cefali\*

Application No. : 08/960,557 Confirmation No. :

Filed : October 31, 1997

For : METHODS FOR TREATING HYPERLIPIDEMIA WITH  
INTERMEDIATE RELEASE NICOTINIC ACID  
COMPOSITIONS HAVING UNIQUE PHARMACEUTICAL  
CHARACTERISTICS

Group : 1615

Examiner : James M. Spear

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Hon. Commissioner for Patents  
P.O. Box 2327  
Arlington, Virginia 22202

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.56 AND 1.97(b)

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicant,  
through his representatives, makes of record the following  
documents, copies of which are included:†

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\* The inventor on file for this application is Eugenio A. Cefali. A Request to Correct Inventorship under 37 C.F.R. § 1.48(a) to add David J. Bova as a co-inventor was filed on January 16, 2003 and is currently pending.

† For the convenience of the Examiner, a completed Form PTO-1449 listing these documents is attached hereto in duplicate

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<sup>†</sup> This symbol indicates documents cited by Barr Laboratories in connection with litigation between Kos Pharmaceuticals and Barr Laboratories currently pending in the Southern District of New York. Kos Pharmaceuticals is the assignee of record of the pending application.

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The above-identified application is a continuation-in-part of United States application 08/814,974 ("the '974 application"), filed March 6, 1997, now United States patent 6,129,930 ("the '930 patent"); which is a continuation-in-part of United States application 08/368,378, filed January 14, 1995, now United States patent 6,080,428 ("the '428 patent"); which is a continuation-in-part of United States application 08/124,392, filed September 20, 1993, now abandoned.

Applicant makes of record the documents listed below, from litigations involving the '930 patent, the '428 patent and United States patent 6,406,715, which claims priority from the '974 application:

\*\* Complaint, filed by Kos Pharmaceuticals, Inc. against Barr Laboratories on March 4, 2002, in Civil Action No. 02 CV 1683.

\*\* First Amended Complaint, filed by Kos Pharmaceuticals, Inc. on March 11, 2002, in Civil Action No. 02 CV 1683.

\*\* Answer To First Amended Complaint, filed by Barr Laboratories on March 25, 2002, in Civil Action No. 02 CV 1683.

\*\* Reply To Counterclaims, filed by Kos Pharmaceuticals, Inc. on April 15, 2002, in Civil Action No. 02 CV 1683.

\*\* Amended Answer To First Amended Complaint, filed by Barr Laboratories on August 19, 2002, in Civil Action No. 02 CV 1683.

\*\* Complaint, filed by Kos Pharmaceuticals, Inc. on August 13, 2002, in Civil Action No. 02 CV 6409.

\*\* Answer To Complaint, filed by Barr Laboratories on September 3, 2002 in Civil Action No. 02 CV 6409.

\*\* Complaint, filed by Kos Pharmaceuticals, Inc. on November 12, 2002, in Civil Action No. 02 CV 8995.

\*\* Answer To Complaint, filed by Barr Laboratories on December 3, 2002 in Civil Action No. 02 CV 8995.

\*\* Reply To Counterclaims And Counterclaims For Declaratory Judgment, filed by Kos Pharmaceuticals, Inc. on March 4, 2003 in Civil Action No. 02 CV 8995.

The majority of the art cited herein has been previously considered by the Examiner in the applications, from which this application claims priority. Art that is being cited to the Examiner for the first time is indicated by asterisks on this Statement and by a flag on the document itself.

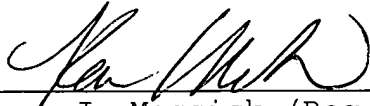
Applicant requests that the above-cited documents be:

- (1) fully considered by the Examiner during the course of the examination of this application; and
- (2) printed on any patent that may issue from this application.

Applicant also requests that a copy of Form PTO-1449,  
as considered and initialled by the Examiner, be returned to the  
undersigned with the next Communication.

Respectfully submitted,

Date: 3/17/03

  
\_\_\_\_\_  
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<b>FORM PTO-1449</b>  <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>ATTY. DOCKET NO.</b> 32892.00023	<b>APPLN. NO.</b> 08/960,557
	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	Re. 29,652	05/30/1978	Fields et al.			RECEIVED TECH CENTER 1600/2900 03 MAR 20 PM 1:25
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	2,957,804	10/25/1960	Schuyler			
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DATE CONSIDERED

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	<b>APPLICANT</b> Eugenio A. Cefali	<b>CONFIRMATION NO.</b>
	<b>FILING DATE</b> October 31, 1997	<b>GROUP</b> 1615

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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,348,399	09/07/1982	Shepherd			
	4,353,887	10/12/1982	Hess et al.			
	4,357,469	11/02/1982	Schor			
	4,361,546	11/30/1982	Stricker et al.			
	4,362,711	12/07/1982	Cerami			
	4,367,217	01/04/1983	Gruber et al.			
	4,369,172	01/18/1983	Schor et al.			
	4,375,468	03/01/1983	Dunn			
	4,382,143	05/03/1983	Shepherd			
	4,389,393	06/21/1983	Schor et al.			
	4,428,951	01/31/1984	Hata et al.			
	4,432,966	02/21/1984	Zeitoun et al.			
	4,440,940	04/03/1984	Shepherd			
	4,452,775	06/05/1984	Kent			
	4,454,108	06/12/1984	Iida et al.			
	4,455,298	06/19/1984	McFarlane et al.			
	4,457,907	07/03/1984	Porter et al.			
	4,461,759	07/24/1984	Dunn			
	4,465,660	08/14/1984	David et al.			
	4,472,436	09/18/1984	Hooper			
	4,478,819	10/23/1984	Hercelin et al.			
	4,485,105	11/27/1984	Shepherd			
	4,505,890	03/19/1985	Jain et al.			
	4,522,804	06/11/1985	Dunn			
	4,525,345	06/25/1985	Dunn et al.			

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	4,539,198	09/03/1985	Powell et al.			
	4,540,566	09/10/1985	Davis et al.			
	4,547,359	10/15/1985	Zierenberg et al.			
	4,556,678	12/03/1985	Hsiao et al.			
	4,568,547	02/04/1986	Herschler			
	4,571,333	02/18/1986	Hsiao			
	4,576,604	03/18/1986	Guittard et al.			
	4,603,142	07/29/1986	Burger et al.			
	4,605,666	08/12/1986	Schmidt et al.			
	4,610,870	09/09/1986	Jain et al.			
	4,624,950	11/25/1986	Sasaki et al.			
	4,657,757	04/14/1987	Hanna et al.			
	4,673,405	06/16/1987	Guittard et al.			
	4,678,516	07/07/1987	Alderman et al.			
	4,680,323	07/14/1987	Lowey			
	4,684,516	08/04/1987	Bhutani			
	4,690,824	09/01/1987	Powell et al.			
	4,692,337	09/08/1987	Ukigaya et al.			
	4,695,467	09/22/1987	Uemura et al.			
	4,695,591	09/22/1987	Hanna et al.			
	4,695,910	09/22/1987	Maruyama et al.			
	4,696,762	09/29/1987	Sander et al.			
	4,704,285	11/03/1987	Alderman			
	4,708,834	11/24/1987	Cohen et al.			
	4,710,519	12/01/1987	Finnan et al.			

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	4,713,245	12/15/1987	Ando et al.			
	4,729,895	03/08/1988	Makino et al.			
	4,734,285	03/29/1988	Alderman			
	4,744,907	05/17/1988	Klimchak et al.			
	4,747,881	05/31/1988	Shaw et al.			
	4,749,575	06/07/1988	Rotman			
	4,752,479	06/21/1988	Briggs et al.			
	4,753,801	06/28/1988	Oren et al.			
	4,755,544	07/05/1988	Makino et al.			
	4,756,911	07/12/1988	Drost et al.			
	4,758,581	07/19/1988	Scherm et al.			
	4,759,923	07/26/1988	Buntin et al.			
	4,764,374	08/16/1988	Grimberg			
	4,775,483	10/04/1988	Mookerjea et al.			
	4,775,535	10/04/1988	Lowey			
	4,777,042	10/11/1988	Toda et al.			
	4,784,858	11/15/1988	Ventouras			
	4,789,549	12/06/1988	Khan et al.			
	4,792,452	12/20/1988	Howard et al.			
	4,792,554	12/20/1988	Elben et al.			
	4,794,115	12/27/1988	Takahasi et al.			
	4,795,327	01/03/1989	Gaylord et al.			
	4,795,642	01/03/1989	Cohen et al.			
	4,795,644	01/03/1989	Zentner			
	4,803,079	02/07/1989	Hsiao et al.			

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	4,803,081	02/07/1989	Falk et al.			
	4,812,316	03/14/1989	Rossi et al.			
	4,814,183	03/21/1989	Zentner			
	4,814,354	03/21/1989	Ghere-Sellassie et al.			
	4,824,672	04/25/1989	Day et al.			
	4,824,677	04/25/1989	Shah et al.			
	4,828,836	05/09/1989	Elger et al.			
	4,830,859	05/16/1989	Finnan			
	4,834,965	05/30/1989	Martani et al.			
	4,834,985	05/30/1989	Elger et al.			
	4,837,032	06/06/1989	Ortega			
	4,839,177	06/13/1989	Colombo et al.			
	4,842,863	06/27/1989	Nishimura et al.			
	4,844,907	07/04/1989	Elger et al.			
	4,849,229	07/18/1989	Gaylord et al.			
	4,851,232	07/25/1989	Urquhart et al.			
	4,851,233	07/25/1989	Khan et al.			
	4,855,143	08/08/1989	Lowey			
	4,857,336	08/15/1989	Khanna et al.			
	4,866,058	09/12/1989	Izydore et al.			
	4,871,548	10/03/1989	Edgren et al.			
	4,882,167	11/21/1989	Jang			
	4,886,669	12/12/1989	Ventouras			
	4,888,178	12/19/1989	Rotini et al.			
	4,892,741	01/09/1990	Ohm et al.			

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	4,911,917	03/27/1990	Kuhrts			
	4,915,952	04/10/1990	Ayer et al.			
	4,920,115	04/24/1990	Nestler et al.			
	4,920,123	04/24/1990	Beyer, Jr.			
	4,925,905	05/15/1990	Boeckh et al.			
	4,935,246	06/19/1990	Ahrens			
	4,940,588	07/10/1990	Sparks et al.			
	4,942,040	07/17/1990	Ragnarsson et al.			
	4,946,870	08/07/1990	Partain, III et al.			
	4,946,963	08/07/1990	Izydore et al.			
	4,950,689	08/21/1990	Yang et al.			
	4,952,402	08/28/1990	Sparks et al.			
	4,959,478	09/25/1990	Möller et al.			
	4,963,367	10/16/1990	Ecanow			
	4,965,252	10/23/1990	Kuhrts			
	4,966,768	10/30/1990	Michelucci et al.			
	4,968,508	11/06/1990	Oren et al.			
	4,970,081	11/13/1990	Frisbee			
	4,973,468	11/27/1990	Chiang et al.			
	4,973,469	11/27/1990	Mulligan et al.			
	4,983,398	01/08/1991	Gaylord et al.			
	4,990,535	02/05/1991	Cho et al.			
	4,992,278	02/12/1991	Khanna			
	4,994,267	02/19/1991	Sablotsky			
	4,994,276	02/19/1991	Baichwal et al.			

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	4,996,058	02/26/1991	Sinnreich			
	4,997,658	03/05/1991	Alberts et al.			
	4,999,380	03/12/1991	Berger et al.			
	5,002,774	03/26/1991	Agrawala et al.			
	5,009,895	04/23/1991	Lui			
	5,010,105	04/23/1991	Lee			
	5,011,947	04/30/1991	Catt et al.			
	5,015,479	05/14/1991	Mulligan et al.			
	5,023,245	06/11/1991	Kuhrts			
	5,025,012	06/18/1991	Miura et al.			
	5,030,653	07/09/1991	Trivedi			
	5,032,406	07/16/1991	Dansereau et al.			
	5,034,528	07/23/1991	Izydore et al.			
	5,039,341	08/13/1991	Meyer et al.			
	5,047,248	09/10/1991	Calanchi et al.			
	5,049,696	09/17/1991	Lee et al.			
	5,096,714	03/17/1992	Kuhrts			
	5,100,675	03/31/1992	Cho et al.			
	5,110,817	05/05/1992	Beyer, Jr.			
	5,110,940	05/05/1992	Sit et al.			
	5,116,610	05/26/1992	Broaddus			
	5,126,145	06/30/1992	Evenstad et al.			
	5,128,142	07/07/1992	Mulligan et al.			
	5,130,333	07/14/1992	Pan et al.			
	5,132,116	07/21/1992	Sournac et al.			

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	5,133,974	07/28/1992	Paradissis et al.			
	5,145,678	09/08/1992	Gakic et al.			
	5,167,964	12/01/1992	Muhammad et al.			
	5,169,638	12/08/1992	Dennis et al.			
	5,169,639	12/08/1992	Baichwal et al.			
	5,169,640	12/08/1992	France et al.			
	5,171,570	12/15/1992	Takemori et al.			
	5,178,854	01/12/1993	Asami et al.			
	5,182,298	01/26/1993	Helms et al.			
	5,188,839	02/23/1993	Pearmain			
	5,190,940	03/02/1993	Commons et al.			
	5,190,970	03/02/1993	Pan et al.			
	5,196,440	03/23/1993	Bertolini et al.			
	5,211,958	05/18/1993	Akkerboom et al.			
	5,213,808	05/25/1993	Bar-Shalom et al.			
	5,256,689	10/26/1993	Chiang			
	5,258,401	11/02/1993	Berger et al.			
	5,260,305	11/09/1993	Dennick			
	5,262,165	11/16/1993	Govil et al.			
	5,262,435	11/16/1993	Joshua et al.			
	5,264,226	11/23/1993	Graille et al.			
	5,268,181	12/07/1993	O'Neill et al.			
	5,278,067	01/11/1994	Dawson et al.			

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	5,286,736	02/15/1994	Soyka et al.			
	5,314,697	05/24/1994	Kwan et al.			

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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	603 690	08/16/1960	Canada				
	0 109 320	05/23/1984	EP				
	0 126 453	11/28/1984	EP				
	0 349 235 A2	01/03/1990	EP				
	0 577 504 A1	01/05/1994	EP				
	1 302 362	07/23/1962	France				
	40-2053	02/03/1965	Japan				
	46-18151	05/20/1971	Japan				
	55-049312	09/04/1980	Japan				
	2 141 338	12/19/1984	UK				
	2 154 874	09/18/1985	UK				
	WO84/00104	01/19/1984	PCT				

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